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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,414	07/10/2003	Ben C. Askew	20610YDA	6800
210	7590	02/23/2006	EXAMINER	
MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907			TRUONG, TAMTHOM NGO	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/618,414

Applicant(s)

ASKEW ET AL.

Examiner

Tamthom N. Truong

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12-19-05 (Election).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-24 is/are pending in the application.
4a) Of the above claim(s) 10-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 9 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7-10-03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election with traverse the invention of Group I in the reply of 12-19-05 is acknowledged. Group I includes claims 1-7 and 9 (in part) which are drawn to the compound of formula (I) wherein X is *pyrimidinyl* or *tetrahydropyrimidinyl*, and pharmaceutical composition thereof.

Claim 8 is cancelled.

Claims 1-7 and 9-24 are pending.

Claims 10-24 are withdrawn as being drawn to the non-elected subject matter.

Claims 1-7 and 9 are considered with respect to the compound of formula (I) wherein X is *pyrimidinyl* or *tetrahydropyrimidinyl*, and pharmaceutical composition thereof.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-6 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

a. Claim 1 recites R⁴ representing specific rings, and also representing "*mono, di, and tri-substituted aryl wherein...two adjacent substituents together with the carbon atoms to which they are attached join to form a five- or six-membered saturated or*

unsaturated ring containing 1 or 2 heteroatoms...". The limitation of 'an aryl group with two substituents forming a ring' appears as a broader limitation of specific bicycles such as *benzimidazolyl, benzofuryl, benzothienyl, quinoxalinyl, ...etc.*

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

- b. Claim 2 is inconsistent with claim 1 because it recites Y as $-\text{CH}_2\text{CH}_2-$ whereas claim 1 requires Y-Z to be $-\text{CH}_2\text{CH}_2-$.
- c. Claims 2-6 and 9 are rejected as being dependent on claim 1, and carrying over the indefinite limitations.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims 1 and 9 are rejected under 35 U.S.C. 102(a) as being anticipated by **Askew et. al.** (WO 99/31061). On page 150, Askew et. al. disclose compound # 26-6 which reads on the instant formula (I) with the following substituents:

- i. X is pyrimidinyl;
- ii. Y-Z is $\text{-CONR}^3\text{-}$;
- iii. R^2 is amino, and at the 2nd position of the pyrimidinyl ring;
- iv. R^3 is hydrogen;
- v. R^4 is quinolyl;
- vi. R^5 is hydrogen.

The pharmaceutical composition recited in the instant claim 9 can also be found on page 190 of WO'061.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by the following references:

- a. **Askew et. al.** (US 6,048,861 or US'861): See compound 26-6 on columns 95-96;
- b. **Duggan et. al.** (US 6,297,249 B1 or US'249): See compound 26-6 on columns 85-86.

The disclosed compound reads on the claimed formula I with the following substituents:

- i. X is pyrimidinyl;
- ii. Y-Z is $-\text{CONR}^3-$;
- iii. R^2 is amino, and at the 2nd position of the pyrimidinyl ring;
- iv. R^3 is hydrogen;
- v. R^4 is quinolyl;

vi. R^5 is hydrogen.

The pharmaceutical composition recited in the instant claim 9 can also be found on column 126 of US'249, and column 136 of US'861.

The applied reference has a common inventor and common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claims 1-6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Askew et. al.** (WO'061).

On page 150, Askew et. al. disclose compound # 26-6 which reads on the instant formula (I) in claim 1 with the following substituents:

- i. X is pyrimidinyl;
- ii. Y-Z is $-\text{CONR}^3-$;
- iii. R^2 is amino, and at the 2nd position of the pyrimidinyl ring;
- iv. R^3 is hydrogen;
- v. R^4 is quinolyl;
- vi. R^5 is hydrogen.

The disclosed compound differs from those recited in the instant claims 2-6 by not having $-\text{CH}_2\text{CH}_2-$. However such a difference can be resolved by the definition of Z on pages 33-34 of WO'061. Variable Z of WO'061 represents only 5 moieties, namely $-\text{C}(=\text{O})\text{NR}^4-$, $-\text{NR}^4\text{C}(=\text{O})-$, $-\text{NR}^4\text{C}(=\text{O})-\text{NR}^4$, $-\text{CH}_2\text{CH}_2-$, or $-\text{CH}=\text{CH}-$. Thus, there is equivalent teaching for $-\text{C}(=\text{O})\text{NR}^4-$ and $-\text{CH}_2\text{CH}_2-$. Furthermore, other species in WO'061 (e.g., compounds 15-7a and 15-7b on page 116) have $-\text{CH}_2\text{CH}_2-$ in the place of $-\text{C}(=\text{O})\text{NR}^4-$.

With the equivalent teaching in the definition of Z as well as species on page 116, the skilled chemist would have been motivated to select and make compounds of the claimed

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formula (I) wherein Y-Z is $-\text{CH}_2\text{CH}_2-$ because said compounds would have been expected to be integrin receptor antagonists as well.

Thus, at the time that the invention was made, it would have been obvious to make and use compounds of the claimed formula I in view of the teaching above.

Claim Objections


5. Claim 7 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Also, claim 7 still recites many species that do not belong to the elected group.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

2-8-06


Tamthom N. Truong
Examiner
Art Unit 1624


JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600